
PDA
Parenteral Drug Association


BioPhorum

The Science, Implications and Implementation of PUPSIT (Pre-Use Post Sterilization Integrity Testing) – A 3 Part Webinar Series

Sept 1: *The Role of PUPSIT in the Assurance of Sterilising Filtration*

Sept 8: *Assessing the Risk of Filter Masking*

Sept 21: *Practical Implications and Decision Making of PUPSIT*

Sterile Filtration Quality Risk Management (SFQRM) Consortium

Companies have struggled with the implementation of the PUPSIT(Pre-Use Post Sterilizaiton Integrity Testing) requirement as EU and other regulatory authorities have increased their enforcement of its use for sterile products.

To address this issue PDA and BioPhorum formed the Sterile Filtration Quality Risk Management (SFQRM) consortium in 2017.

The consortium brought together a group of over 50 subject matter experts, over a 3-year period, and are now ready to share their groundbreaking results and insight.

Today's Expert Q&A Panel

Dieter Bachmann	Director, Aseptic Processing, Johnson and Johnson
Hal Baseman	Chief Operating Officer at Valsource Inc.
Steve Ensign	Senior Consultant Engineer, Eli Lilly
Gabriele Gori	VP, Head of Audit & Risk Management, Global Quality, GSK Vaccines
Maik Jornitz	President and CEO of G-CON Manufacturing Inc.
Stephen Lexa	Associate Senior Consultant, Quality, Eli Lilly
Shyam Mehta PhD.	Sr. Scientist, CMC Biologics, Teva Branded Pharmaceuticals
Brian Thome PhD.	Principal Engineer, Parenteral Manufacturing Sciences, Biogen
Carl Weitzmann PhD.	Associate Director, Process Technology Platform, Sanofi Pasteur
Thao Vinh-Le	Senior Manager, Secondary Transversal Support – MSAT, GSK Vaccines

Today's Presenter

Steve Ensign

Senior Consultant Engineer

Eli Lilly

Mr. Ensign has over 30 years of experience in the pharmaceutical industry and has had numerous assignments in engineering projects and process, TSMS, manufacturing, leadership and Six Sigma (Black Belt) in the parenteral operations area. Previous assignments have included new product development, scale-ups, building and starting up new facilities. His current position is working to increase pre-filled syringe capacity in the US and Europe for current and new products.. Mr. Ensign received a B.S. in Mechanical Engineering from the University of Illinois in 1988 and Six Sigma Black Belt certification in 2005.

-Panelist Bios-

Dieter Bachmann

Director, Aseptic Processing
Johnson and Johnson

Dieter is Director Aseptic Processing at J&Js corporate Sterility Assurance group with a main responsibility for providing standardization, science and education across J&J in the field of aseptic processing technologies. He is a Pharmacist by training with 30+ years of experience and holds a PhD in Pharmaceutical Formulation Technologies. Dieter has worked with small family-owned companies as well as in global business. Since joining Johnson & Johnson in 1998 he held several positions in R&D, Operations and Quality of J&Js Pharma and Medical Device franchises. Alongside business Dieter always engaged in associations work. For 10 years Dieter used to work as a Swiss national delegate on developing monographs for the European Pharmacopeia (EP) at EDQM in Strassburg. He is a frequent presenter and active member of PDA and ISPE. Dieter engages at the German DIN/NA063 and ISO TC198. Since 2019 Dieter is the global convenor for ISO TC198/WG9 Aseptic Processing.

Hal Baseman

Chief Operating Officer at Valsource Inc

Mr. Baseman is the Chief Operating Officer at Valsource Inc. with over 40 years in pharmaceutical industry. He has held PDA positions as Board Chair, SAB Co-chair, Co-lead for Aseptic Processing Points to Consider, Process Validation IG, TR 22, 44, and 60, and is a long standing member of TRI faculty. Hal co-chairs the Annex 1 response team, Portfolio Steering Committee, and MSOP and is a member of the QRM for Aseptic Processing Standards task force and the PUPSIT consortium committee. Hal holds MBA from LaSalle University and B.S. Biology from Ursinus College.

Gabriele Gori

Vice President, Head of Audit & Risk Management, Global Quality

GSK Vaccines

Gabriele Gori has been in the sterile Pharmaceutical / Vaccine/Medical Device business since 1994 in different local and global roles in multinational companies, including, Bausch & Lomb, Chiron, Novartis and GlaxoSmithKline. His experience covers R&D, Engineering, Quality Control, Quality Assurance and GXP Compliance. Since September 2015 he has been in the role of Vice President, Global Head of Audit and Risk Management at GlaxoSmithKline Vaccines.

Maik W. Jornitz

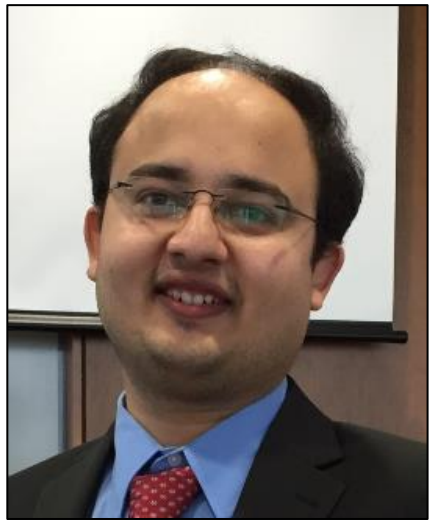
President and CEO of G-CON Manufacturing Inc

Mr. Jornitz is a technical expert with over 30 years of experience in bioprocesses, especially sterilizing grade filtration and single-use technologies, including regulatory requirements, integrity testing, systems design, and optimization. Jornitz has published 11 books, 18 book chapters and over 100 scientific papers. He is the former Chair of the PDA Board of Directors and Science Advisory Board, and member of multiple PDA Task Forces. He is working member of Biophorum, ASTM, an advisory board member of the Biotechnology Industry Council, ICAV and multiple science journals. He recently has been recognized as one of the top ten global industry influencers. As a faculty member of various training activities, including PDA TRI, he trains members of the industry and regulatory authorities on a frequent basis. He received his M.Eng. in Bioengineering at the University of Applied Sciences in Hamburg, Germany and accomplished the PED program at IMD Business School in Lausanne, Switzerland

Stephen Lexa

Associate Senior Consultant, Quality, Eli Lilly

Mr Lexa has spent over 12 years in parenteral manufacturing spanning clinical, commercial, and extemporaneous prep applications. He has experience in new facility construction as well as sterile area renovations. Steve has held a variety of operations and quality leadership and project roles, including those involving facility/equipment design and quality system integration. He also provides expertise in areas of sterility assurance, risk-management principles, and applied risk tools.



Shyam Mehta PhD.

Senior Scientist, Drug Product Development and Operations, CMC Biologics
Teva Branded Pharmaceuticals

Shyam is a biopharmaceutical scientist with expertise in protein stability and aggregation, biophysical characterization of proteins, protein particle characterization, analytical chemistry and protein expression and purification, protein formulation development, process development and Validation of fill-finish manufacturing of Biologics, Aseptic Processing of Parenteral Products.

Brian Thome PhD.

Principal Engineer, Parenteral Manufacturing Sciences, Biogen

Brian is a process engineer who has worked across the fill finish spectrum over his twelve year career in the biopharma industry including formulations, lyophilization, process development, analytics and technology transfer. The last ten years have been spent at Biogen where he has led tech parenteral drug product technology transfers to external manufacturing partners as part of the launch of three commercial products. He currently leads a team responsible for process validation and ongoing technical process ownership for Biogen's commercial parenteral products. Brian is from Seattle, Washington, USA and currently lives in Zürich, Switzerland. He received his doctorate in Chemical Engineering from Washington State University.

Carl Weitzmann PhD

Associate Director, Process Technology Platform

Sanofi Pasteur

Carl Weitzmann is Associate Director in the Process Technology platform at Sanofi Pasteur, located at the vaccines production site in Swiftwater Pennsylvania, with responsibility for filtration processes. He has held positions at Wyeth (Pearl River) and at Sanofi in R&D QA, R&D Process Development, and Manufacturing Technology, spanning development and technology transfer of multiple vaccine and biological products. He holds a Ph.D. in Biochemistry from the University of Pennsylvania, with a strong background in enzymology, protein chemistry, and molecular biology, 20 years' experience in the pharmaceutical industry dealing with process, aseptic process, cleaning, and filter validation, and 10 years' experience in filter manufacture and validation.

Thao Vinh-Le

Senior Manager, Secondary Transversal Support – MSAT
GSK Vaccines

Thao Vinh-Le is a Certified Industrial Pharmacist with a master degree in Pharmaceutical Engineering and Industrial Technology. Having over 19 years of (bio)pharma international experiences and over than 10 years within GSK Vaccines – MSAT team which is mainly in charge of Transversal Project, Quality Improvement Program and Troubleshooting in Commercial Manufacturing Process. Over the last 4 years, Thao has acting more specifically as the GSK Vaccines PUPSIT expert, following the PUPSIT risk evolution and in charge of the development of the PUPSIT technology deployment.